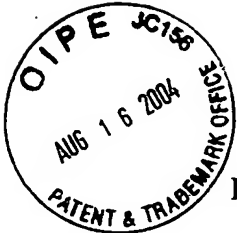


IFW



PATENT

Attorney Docket No. A-71486-2
Dorsey File No. 463077-00240

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

DESJARLAIS et al.

Serial No.: 10/611,363

Filing Date: July 1, 2003

For: *Novel Variants of RANKL Protein*

Examiner: To Be Assigned

Art Unit: 1647

CERTIFICATE OF MAILING

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Date: August 13, 2004
Signed: Careyna Peralta
Careyna Peralta

**INFORMATION DISCLOSURE STATEMENT
AND
STATEMENT OF RELATEDNESS**

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants wish to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying Form PTO/SB/08A-B, Substitute for form PTO 1449. This application is a continuation-in-part of the following related U.S. Application - Serial No. 10/338,785, filed January 6, 2003 (pending). The references cited on the accompanying form PTO/SB/08A-B, Substitute for form PTO-1449, not marked with an asterisk (*), were previously disclosed in the above-mentioned application and in accordance with 37 C.F.R. § 1.98(d), no copies of these references are enclosed.

Serial No.: 10/611,373
Filing Date: July 1, 2003

Further, in accordance with 1273 Off. Gaz. Pat. Off. 1, 8/5/2003, no copies of U.S. patents and U.S. published applications are enclosed. Copies of all other references are enclosed.

With respect to patent applications, the applicants point out their duty under M.P.E.P. §2001.06(b) to disclose relevant patent applications of which they are aware. To this end, the applicants draw the Examiner's attention to the following patent applications:

1. U.S.S.N. 10/888,748, filed July 9, 2004;
2. U.S.S.N. 10/611,399, filed July 1, 2003;
3. U.S.S.N. 10/336,242, filed January 3, 2003;
4. U.S.S.N. 10/794,751, filed March 5, 2004; and
5. U.S.S.N. 10/820,465, filed March 31, 2004.

None of the foregoing references is believed to disclose the invention as claimed. Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application. Submission of the present document shall not be construed as an admission that a search has been made or that better art does not exist.

As far as is known to the undersigned, this Information Disclosure Statement is being filed within three months of the filing date of a national application, within three months of the date of entry of the national state in an international application, or before the mailing date of a first Office Action on the merits as set forth in 37 C.F.R. § 1.97(b), and therefore no fee is required.

While no further fee is believed to be due, if this belief is in error, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be

Serial No.: 10/611,373
Filing Date: July 1, 2003

required, or credit any overpayment to Deposit Account No. 50-2319 (Our Order No. 463077-00240 (A-71486-2/RMS/RMK)).

Please direct any calls in connection with this application to the undersigned at
(415) 781-1989.

Respectfully submitted,
DORSEY & WHITNEY LLP

Dated: 8/13/04
Dorsey & Whitney LLP
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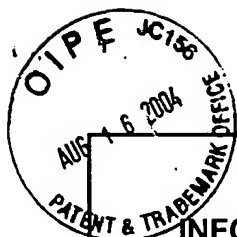
BY: 

Renee M. Kosslak, Reg. No. 47,717 for
Robin M. Silva, Reg. No. 38,304

Customer Number: 32940

Attachments:

Form PTO/SB/8A-B, Substitute for form PTO 1449
5 references



Substitute for form 1449A/PTO
(Modified)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	10/611,363
Filing Date	July 1, 2003
First Named Inventor	DESJARLAIS, John R.
Art Unit	1647
Examiner Name	To Be Assigned
Attorney Docket Number	A-71486-2

Sheet 1 of 6

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	5,843,678	12-01-1998	Boyle	
	A2	6,017,729	01-25-2000	Anderson et al.	
	A3 *	6,188,965 B1	02-13-2001	Mayo et al.	
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	A6 *	6,403,312 B1	06-11-2002	Dahiyat et al.	
	A7 *	6,708,120 B1	03-16-2004	Mayo et al.	
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	A21 *	2003/0219864 A1	11-27-2003	Desjarlais et al.	
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	A23 *	2004/0043430 A1	03-04-2004	Dahiyat et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document Country Code ² Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	B1 *	EP 0 974 111 B1	01-26-2000	California Institute of Technology		
	B2 *	WO 98/47089 A1	10-22-1998	California Institute of Technology		
	B3	WO 99/29865 A3	06-17-1999	The Rockefeller University		
	B4	WO 00/15807 A1	03-23-2000	M & E Biotech		
	B5 *	WO 00/23564 A2	04-27-2000	Xencor, Inc.		

Examiner Signature	Date Considered
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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English Language Translation is attached.

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<p>Substitute for form 1449A/PTO (Modified)</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>				Complete if Known	
				Application Number	10/611,363
				Filing Date	July 1, 2003
				First Named Inventor	DESJARLAIS, John R.
				Art Unit	1647
				Examiner Name	To Be Assigned
Sheet	2	of	6	Attorney Docket Number	A-71486-2

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	B6 *	WO 01/59066 A2, A3	08-16-2001	Xencor, Inc.		
	B7 *	WO 03/014325 A2, A3	02-20-2003	Xencor		
	B8	WO 03/033663 A2	04-24-2003	Barnes-Jewish Hospital		
	B9	WO 03/033664 A2	04-24-2003	Barnes-Jewish Hospital		

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ⁶
	C1	ADLER, S.H., and TURKA L.A., "Immunotherapy as a means to induce transplantation tolerance," Curr Opin Immunol, 2002 Oct, 14(5):660-5.				
	C2	ALATALO S.L., et al., "Rapid Screening Method for Osteoclast Differentiation in Vitro That Measures Tartrate-resistant Acid Phosphatase 5b Activity Secreted into the Culture Medium," Clin Chem, 2000 Nov, 46(11):1751-4.				
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	C4	ARRON JR, and CHOI Y, "Bone versus immune system," Nature, 2000 Nov 30, 408(6812):535-6.				
	C5	ATKINS GJ, et al., "Osteoprotegerin inhibits osteoclast formation and bone resorbing activity in giant cell tumors of bone," Bone, 2001 Apr, 28(4):370-7.				
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Examiner Signature	Date Considered
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			Art Unit	1647	
			Examiner Name	To Be Assigned	
Sheet	3	of	6	Attorney Docket Number	A-71486-2

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	C14	DEYAMA Y, et al., "Histamine stimulates production of osteoclast differentiation factor/receptor activator of nuclear factor-kappaB ligand by osteoblasts," Biochem Biophys Res Commun., 2002 Oct 25, 298(2):240-6.		
	C15	FATA JE, et al., "The osteoclast differentiation factor osteoprotegerin-ligand is essential for mammary gland development," Cell., 2000 Sep 29, 103(1):41-50.		
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	C22	HOFBAUER LC, et al., "Interleukin-1beta and tumor necrosis factor-alpha, but not interleukin-6, stimulate osteoprotegerin ligand gene expression in human osteoblastic cells," Bone, 1999 Sep, 25(3):255-9.		
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Examiner Signature				Date Considered

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	C34	LACEY DL, et al., "Osteoprotegerin ligand is a cytokine that regulates osteoclast differentiation and activation," Cell, 1998 Apr 17, 93(2):165-76.		
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	C38	LEAN JM, et al., "Osteoclast lineage commitment of bone marrow precursors through expression of membrane-bound TRANCE," Bone, 2000 Jul, 27(1):29-40.		
	C39	LI J, et al., "RANK is the intrinsic hematopoietic cell surface receptor that controls osteoclastogenesis and regulation of bone mass and calcium metabolism," Proc Natl Acad Sci U S A, 2000 Feb 15, 97(4):1566-71.		
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	C45	McHUGH KP, et al., "Mice lacking beta3 integrins are osteosclerotic because of dysfunctional osteoclasts," J Clin Invest., 2000 Feb, 105(4):433-40.		
	C46	MENAA C, et al., "Enhanced RANK ligand expression and responsivity of bone marrow cells in Paget's disease of bone," J Clin Invest., 2000 Jun, 105(12):1833-8.		
	C47	NAKAGAWA N, et al., "RANK is the essential signaling receptor for osteoclast differentiation factor in osteoclastogenesis," Biochem Biophys Res Commun., 1998 Dec 18, 253(2):395-400.		
	C48	NAKASHIMA T, et al., "Protein expression and functional difference of membrane-bound and soluble receptor activator of NF-kappaB ligand: modulation of the expression by osteotropic factors and cytokines," Biochem Biophys Res Commun., 2000 Sep 7, 275(3):768-75.		
	C49	OYAJOB BO, et al., "Therapeutic efficacy of a soluble receptor activator of nuclear factor kappaB-IgG Fc fusion protein in suppressing bone resorption and hypercalcemia in a model of humoral hypercalcemia of malignancy," Cancer Res., 2001 Mar 15, 61(6):2572-8.		
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	C51	QUINN JM, et al., "A combination of osteoclast differentiation factor and macrophage-colony stimulating factor is sufficient for both human and mouse osteoclast formation in vitro," Endocrinology, 1998 Oct, 139(10):4424-7.		
	C52	QUINN JM, et al., "The generation of highly enriched osteoclast-lineage cell populations," Bone, 2002 Jan, 30(1):164-70.		

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			Art Unit	1647	
			Examiner Name	To Be Assigned	
Sheet	5	of	6	Attorney Docket Number	A-71486-2

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	† ⁶	
	C53	RODAN GA, and Martin TJ, "Therapeutic approaches to bone diseases," Science, 2000 Sep 1, 289(5484):1508-14.		
	C54	ROMAS E, et al., "Involvement of receptor activator of NFkappaB ligand and tumor necrosis factor-alpha in bone destruction in rheumatoid arthritis," Bone, 2002 Feb, 30(2):340-6.		
	C55	SABOKBAR A, et al., "Two distinct cellular mechanisms of osteoclast formation and bone resorption in periprosthetic osteolysis," J Orthop Res., 2003 Jan, 21(1):73-80.		
	C56	SAIDENBERG KERMANAC'H N, et al., "Osteoprotegerin and inflammation," Eur Cytokine Netw., 2002 Apr-Jun, 13(2):144-53.		
	C57	SCHLONDORFF J, et al., "Biochemical and pharmacological criteria define two shedding activities for TRANCE/OPGL that are distinct from the tumor necrosis factor alpha convertase," J Biol Chem., 2001 May 4, 276(18):14665-74.		
	C58	SCHOPPET M, et al., "RANK ligand and osteoprotegerin: paracrine regulators of bone metabolism and vascular function," Arterioscler Thromb Vasc Biol., 2002 Apr 1, 22(4):549-53.		
	C59	SENIOR K., "Vaccinating against bone destruction," Drug Discov Today, 2001 Dec 15, 6(24):1243-1244.		
	C60	SHEVDE NK, et al., "Estrogens suppress RANK ligand-induced osteoclast differentiation via a stromal cell independent mechanism involving c-Jun repression," Proc Natl Acad Sci U S A, 2000 Jul 5, 97(14):7829-34.		
	C61	SRIVASTAVA S, et al., "Estrogen decreases osteoclast formation by down-regulating receptor activator of NF-kappa B ligand (RANKL)-induced JNK activation," J Biol Chem., 2001 Mar 23, 276(12):8836-40.		
	C62	SUDA T, et al., "Modulation of osteoclast differentiation and function by the new members of the tumor necrosis factor receptor and ligand families," Endocr Rev., 1999 Jun, 20(3):345-57.		
	C63	TAKAHASHI N, et al., "A new member of tumor necrosis factor ligand family, ODF/OPGL/TRANCE/RANKL, regulates osteoclast differentiation and function," Biochem Biophys Res Commun., 1999 Mar 24, 256(3):449-55.		
	C64	TAKAYANAGI H, et al., "RANKL maintains bone homeostasis through c-Fos-dependent induction of interferon-beta," Nature, 2002 Apr 18, 416(6882):744-9.		
	C65	TAKAYANAGI H, et al., "Signaling crosstalk between RANKL and interferons in osteoclast differentiation," Arthritis Res., 2002, 4(Suppl 3):S227-32.		
	C66	TEITELBAUM SL., "Bone resorption by osteoclasts," Science, 2000 Sep 1, 289(5484):1504-8.		
	C67	THEILL LE, et al., "RANK-L and RANK: T cells, bone loss, and mammalian evolution," Annu Rev Immunol., 2002, 20:795-823.		
	C68	TSUDA E, et al., "Isolation of a novel cytokine from human fibroblasts that specifically inhibits osteoclastogenesis," Biochem Biophys Res Commun., 1997 May 8, 234(1):137-42.		
	C69	UDAGAWA N, et al., "Origin of osteoclasts: mature monocytes and macrophages are capable of differentiating into osteoclasts under a suitable microenvironment prepared by bone marrow-derived stromal cells," Proc Natl Acad Sci U S A, 1990 Sep, 87(18):7260-4.		
	C70	VANDERKERKEN K, et al., "Recombinant osteoprotegerin decreases tumor burden and increases survival in a murine model of multiple myeloma," Cancer Res., 2003 Jan 15, 63(2):287-9.		
	C71	WEI S, et al., "Receptor activator of nuclear factor-kappa b ligand activates nuclear factor-kappa b in osteoclast precursors," Endocrinology, 2001 Mar, 142(3):1290-5.		
	C72	WEKERLE T, et al., "Mechanisms of transplant tolerance induction using costimulatory blockade," Curr Opin Immunol., 2002 Oct, 14(5):592-600.		

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			Application Number	10/611,363	
			Filing Date	July 1, 2003	
			First Named Inventor	DESJARLAIS, John R.	
			Art Unit	1647	
			Examiner Name	To Be Assigned	
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	C73	WILLARD D, et al., "Expression, purification, and characterization of the human receptor activator of NF-kappaB ligand (RANKL) extracellular domain," Protein Expr Purif., 2000 Oct, 20(1):48-57.		
	C74	WONG BR, et al., "TRANCE is a novel ligand of the tumor necrosis factor receptor family that activates c-Jun N-terminal kinase in T cells," J Biol Chem., 1997 Oct 3, 272(40):25190-4.		
	C75	WUYTS W, et al., "Evaluation of the role of RANK and OPG genes in Paget's disease of bone," Bone, 2001 Jan, 28(1):104-7.		
	C76	YAMAGISHI T, et al., "Reciprocal control of expression of mRNAs for osteoclast differentiation factor and OPG in osteogenic stromal cells by genistein: evidence for the involvement of topoisomerase II in osteoclastogenesis," Endocrinology, 2001 Aug, 142(8):3632-7.		
	C77	YASUDA H, et al., "Osteoclast differentiation factor is a ligand for osteoprotegerin/osteoclastogenesis-inhibitory factor and is identical to TRANCE/RANKL," Proc Natl Acad Sci U S A, 1998 Mar 31, 95(7):3597-602.		

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